IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF NEW YORK

MARGARET M. MARKER and
RICHARD J. MARKER,

Plaintiffs,

v. **CIVIL ACTION NO. :**

ZIMMER,INC and ZIMMER HOLDINGS, INC.,

JURY TRIAL DEMANDED

Defendants.

COMPLAINT

Jurisdiction and Parties

a. Jurisdiction is vested in this Court by virtue of the provisions of 28 U.S.C. §1332. The amount in controversy herein exceeds the sum of $75,000.00, exclusive of costs and interest.

b. Plaintiff, MARGARET M. MARKER ("Plaintiff"), is an individual and a citizen of Rensselaer County and of the State of NEW YORK.

c. On or about May 2, 2007 , Marc D. Fuchs, M.D., performed surgery on Plaintiff at ALBANY MEDICAL CENTER, and implanted in Plaintiff's hip a Zimmer Durom Cup, a hip replacement implant device which was designed, promoted, manufactured, and sold by Defendants and which is known as Zimmer Durom Cup Hip Implant Device.

d. Due to the implantation of this device in Plaintiff's body, Plaintiff has suffered, and will continue to suffer, severe, permanent physical harm, pain, mental anguish and emotional distress, among other injuries, including, but not limited to dislocation, severe and persistent pain; the implant that did not become or stay implanted, thereby causing dislocation; difficulty getting up from a seated position; lack of strength and endurance .

e. Plaintiff's spouse, RICHARD J. MARKER ("Plaintiff's spouse"), is an individual and a citizen of Rensselaer County and of the State of NEW YORK

f. Defendant, Zimmer, Inc., is a corporation, incorporated under the laws of the State of Delaware has its principle place of business in Warsaw, Indiana.

7. Defendant, Zimmer Holdings,, Inc., is a corporation, incorporated under the laws of the State of Delaware has its principle place of business in Warsaw, Indiana.

General Statement of Facts and Regulatory Background

8. Defendants designed, manufactured, and then promoted, marketed, distributed and sold a variety of Zimmer Durom Cup Hip Implant Devices for surgical implantation into the hips, including the device implanted in Plaintiff's hip.

9. The aforesaid medical hip implant devices, l of which are medical devices that are regulated by the Food and Drug Administration ("FDA") and governed by the Food, Drug and Cosmetic Act ("FDCA") and the Medical Device Amendments ("MDAs") thereto.

10. Zimmer Durom Cup Hip Implant Devices were designed, manufactured, sold and intended to be used in hip replacement surgery in which surgical techniques are applied to cause hip replacement in order to correct various conditions involving the deterioration of the hip joints and bones and hip instability and/or deformity. Generally, these devices consist of components such as a metal shell with a strong plastic liner, replacing the ball and a long metal stem that fits down into the femur. The metal ball is attached or mounted on top of the stem, and a stem implant is inserted into the femoral canal.

11. Zimmer Durom Cup Hip Implant Devices have been classified by the FDA as Class III devices which "present a potential unreasonable risk of illness or injury" and therefore must receive premarket approval from the FDA before they may be commercially distributed

or sold.

12. Neither Defendant Zimmer has never notified Plaintiff or her spouse of any recall or of any problem with the Zimmer Durom Cup Hip Implant Device, even though said Deafen-dants have taken the said device off the marker in July of 2008, due to problems and failures with a large number of said implant or said devices.

13. Marc D. Fuchs, M.D., has never notified Plaintiff or her spouse of any recall or of any problem with the Zimmer Durom Cup Hip Implant device, even though said Defendants Zimmer have taken the said device off the marker in July of 2008, due to problems and failures with a large number of said implant or said devices.

14. Albany Medical Center has never notified Plaintiff or her spouse of any recall or of any problem with the Zimmer Durom Cup Hip Implant device, even though said Defendants have taken the said hip replacement device off the marker in July of 2008, due to problems and failures with a large number of said implant or said devices.

A. Causation and Injury

15. The purpose of the acts and practices was to cause devices intended for use as hip replacement devices to be placed into interstate commerce and to be used in patients, including Plaintiff herein.

16. As a direct and proximate result there, the hip replacement devices offered for sale by Defendants hip replacement devices were placed in interstate commerce, purchased, and surgically implanted as pedicle screw fixation devices in patients including Plaintiff herein, which would not have occurred but for the acts and practices of Defendants.

17. As a direct, proximate, and reasonably foreseeable result of the acts and practices of said Defendants acts and practices Plaintiff has suffered and will continue to suffer

physical harm, including injuries to Plaintiff's hip, hip , spinal nerve roots, and surrounding nerves, cells, tissues, and vascular structures. As a consequence of this, Plaintiff has in the past and will in the future suffer a loss of earnings, an impairment of earning capacity, physical pain, mental anguish, emotional distress, disability, liabilities for medical and rehabilitative expenses and other forms of loss and damage.

AS AND FOR A FIRST CAUSE OF ACTION: Concert of Action

18. Plaintiff realleges each and every allegation set forth in the Paragraphs above and further alleges as follows.

19. Both Defendants' conduct in marketing, promoting, distributing, and selling its medical devices for their intended use as hip replacement, was tortious and constituted a breach of duty in that such conduct involved the introduction or delivery for introduction into interstate commerce of devices that were adulterated or misbranded, the adulteration or misbranding of such devices and the receipt in interstate commerce of devices which were adulterated and misbranded in violation of the FDCA, and in violation of state laws or common law rules which directly or indirectly adopt such federal laws as a standard of conduct.

20. Defendants conduct in marketing, promoting, distributing, and selling its medical devices for their intended use as hip replacement devices, was tortuous in that it was deceptive and materially misleading as set forth above.

21. The Defendants knew, and/or should have known that their conduct constituted a breach of such duties and nonetheless provided substantial injuries and physical and emotional damage to plaintiff.

22. As a direct and proximate result of the conduct described in the preceding paragraphs, spine surgeons in general, and Plaintiff's surgeon in particular, were induced to

cause the purchase and surgical use of Defendants' hip replacement devices for their intended use as hip replacement devices including the device which was surgically implanted into Plaintiff's hip and leg.

23. As a direct and proximate result of Defendants' concerted activities and resulting surgical implantation of Defendants' Zimmer hip replacement device into Plaintiff, Plaintiff has suffered and will continue to suffer severe physical harm, including injuries to the Plaintiff's hip, femur, spinal nerves, spinal nerve roots, and surrounding nerves, tissues, cells and vascular structures. As a result, Plaintiff has in the past and will in the future suffer a loss of earnings, an impairment in earning capacity, physical pain, mental anguish, emotional distress, disability and liabilities for medical and rehabilitation expenses and other forms of loss, injury and damage.

AS AND FOR A SECOND CAUSE OF ACTION:
Fraudulent Marketing and Promotion

24. Plaintiff realleges each and every allegation set forth in the Paragraphs above and further alleges as follows: The claims made in this Count of the Complaint are brought by Plain-tiff against both Defendants Zimmer.

25. As set forth above, at all times material to this case, said Defendants prepared, distributed, or caused to be prepared and distributed videotapes, patient brochures, technique manuals, and catalogs which described the clinical use of Defendants hip replacement devices.

27. In addition, as set forth with greater particularity in this Complaint, Defendants Zimmer caused physicians and engineers, to appear at various symposia, workshops, seminars, training sessions and the like in which spine surgeons received "instruction" concerning Zimmer hip replacement devices.

28. In the videotapes, patient brochures, technique manuals, and presentations which both defendants Zimmer made or caused to be made regarding the use of its devices as hip replacement devices Both Defendants Zimmer expressly or impliedly represented that its devices were safe and effective when used as hip replacement devices in surgery designed to correct hip deformities and instability. Indeed, the patient brochures which Zimmer distributed discusses the use of Zimmer hip replacement devices and falsely promises patients that after hip replacement surgery with such Zimmer hip replacement devices most patients achieve results and are eventually free of pain and better able to participate in all or most of their desired normal daily activities.

29. These representations were made to induce physicians to perform and patients to undergo hip replacement device surgery involving the use of Zimmer hip replacements devices.

30. The representations which Zimmer made to spine surgeons and patients that Zimmer hip replacement devices were safe and effective for use in hip replacement surgery were false and materially misleading.

31. The misrepresentations which Zimmer made and caused to be made with regard to the safety and efficacy of its devices as hip replacement devices were intentionally misleading.

32. In reasonable and justifiable reliance on the misleading representations which Defendants Zimmer made concerning the safety and effectiveness of its devices as hip replacement devices, and induced thereby, Plaintiff"s surgeon implanted a Zimmer hip replacement device in Plaintiff by inserting a Zimmer hip replacement device into the hip and leg bone of Plaintiff.

33. As a direct and proximate result of Defendants Zimmer's conduct and the resulting surgery, Plaintiff has suffered and will continue to suffer physical harm, including injuries to the Plaintiff's hip and leg, spinal nerve roots, and surrounding nerves, tissues, cells and vascular structures. As a consequence of this, Plaintiff has in the past and will in the future suffer a loss of earnings, an impairment in earning capacity, physical pain, mental anguish, emotional distress, disability, liabilities for medical and rehabilitation expenses and other forms of loss, injury and damage.

AS AND FOR A THIRD CAUSE OF ACTION:

Negligent Misrepresentation/Section 402(B) of the Restatement of Torts (Second)

34. Plaintiff realleges each and every allegation set forth in the Paragraphs above and further alleges as follows: The claims made in this Count of the Complaint are brought by Plaintiff against Defendants Zimmer.

35. Defendants Zimmer failed to exercise reasonable care to assure that the representations which it made and caused to be made concerning the safety and effectiveness of its devices for their intended use as hip replacement devices as herein set forth in the Complaint were accurate, truthful, complete and not misleading.

36. In reasonable and justifiable reliance on the misleading representations which Defendants Zimmer made concerning the safety and effectiveness of its devices as hip replacement devices, and induced thereby, Plaintiff's surgeon to implant a Zimmer hip replacement device in Plaintiff by inserting Defendants Zimmer hip replacement device into the hip and leg of Plaintiff.

3g. As a direct and proximate result of Defendants Zimmer's conduct and the resulting surgery, Plaintiff has suffered and will continue to suffer physical harm, including injuries to the

Plaintiff's hip and leg, spinal nerve roots, and surrounding nerves, tissues, cells and vascular structures. As a consequence of this, Plaintiff has in the past and will in the future suffer a loss of earnings, an impairment in earning capacity, physical pain, mental anguish, emotional distress, disability, liabilities for medical and rehabilitation expenses and other forms of loss, injury and damage.

3h. By virtue of the matters set forth in this Complaint, Defendants Zimmer is liable to Plaintiff for negligent misrepresentation and/or under the concept of strict liability set forth in the Restatement of Torts (Second), §402(b).

AS AND FOR A FOURTH CAUSE OF ACTION:

Strict Liability in Tort

3i. Plaintiff realleges each and every allegation set forth in the Paragraphs above and further alleges as follows.

40. The claims made in this Count of the Complaint are brought by Plaintiff against Defendants Zimmer.

40. The hip replacement device which was implanted in Plaintiff was designed, promoted, distributed, marketed and sold by Defendants Zimmer for its intended use as a hip replacement device.

41. The Zimmer hip replacement device used in the Plaintiff was defectively designed for its intended use as a hip replacement device in that, among other things, it would not allow the implant to bond or knit with the device, and the device had an inappropriate degree of stability, and allows for or encourages for dislocations, which are very painful.

42. The Zimmer hip replacement device implanted in Plaintiff contained dangerous manufacturing defects, including, but not limited to, inadequate materials of construction and

inadequate quality control in machining of critical components, and/or inadequate finishing processes, improper design in that it would no allow for the surrounding bone to bond or knit with the said device.

43. Furthermore, Defendants Zimmer failed to adequately warn Plaintiff and Plaintiff's implanting physician that the FDA had never found that Zimmer hip replacement devices were safe and effective for their intended use in the hip replacement device, and that the sale, distribution, promotion and marketing of these devices for their intended use as hip replacement devices constituted the sale of misbranded and adulterated products in violation of the FDCA and FDA regulations.

44. Defendants Zimmer knew, yet improperly failed to provide adequate warnings to Plaintiff and Plaintiff's implanting physician, that every Zimmer IDE designed to show the safety and effectiveness of Zimmer hip replacement devices for their intended use as hip replacement had failed to demonstrate the safety and effectiveness of these devices for that intended use.

45. Defendants Zimmer failed to provide adequate and proper instructions concerning appropriate indications for its devices for their intended use as hip replacement devices, including the device implanted in the Plaintiff, because, among other reasons, it failed to conduct appropriate tests and studies to ascertain what those indications were, and when the Zimmer hip replacements devices were recalled form the market, Zimmer claimed that the problem with the device was that the surgeons were not adequately trained in the implantation procedures .

46. Defendants Zimmer failed to provide appropriate warnings to physicians and surgeons concerning the hazards and side effects the device implanted in Plaintiff, for its intended use as a hip replacement device, because, among other things, it failed to conduct adequate and appropriate tests and studies of the use of its devices for hip replacement.

47. Defendants Zimmer failed to provide appropriate warnings concerning contra-indications to the use of the device implanted in Plaintiff for its intended use as a hip replacement device, because, among other things, it failed to conduct adequate and appropriate studies and tests concerning the use of its devices for hip replacement.

48. As a result of the design defects, manufacturing defects, and failure to provide adequate warnings and instructions with respect to the Zimmer hip replacement device implanted into Plaintiff, this medical device was unsafe, defective and presented an unreasonable risk of harm to Plaintiff in the intended use of the device, i.e. a hip replacement device.

49. Zimmer hip replacement devices, including the device implanted in Plaintiff, are defective, unsafe, and unreasonably dangerous when used for their intended use in the hip and leg, because of the risks described above.

50. The risks of the Zimmer hip replacement device which was implanted in Plaintiff when used for its intended purposes as a hip replacement device far exceed and outweigh any utility of using it, thereby rendering the device unsafe, defective and unreasonably dangerous for its intended use.

51. Moreover, there are, and have been, at all relevant times, superior alternative designs or methods available for stabilization of the hip/spine at substantially less risk of injury and harm to Plaintiff than the Zimmer hip replacement device implanted in Plaintiff when used for its intended purpose as a hip replacement device, thereby rendering the device unsafe, defective and unreasonably dangerous for its intended use.

52. The fact that defendants Zimmer marketed, promoted, and sold its devices for use as hip replacement and failed to complete IDE clinical trials which produced data providing a reasonable assurance that its devices were safe and effective when used as hip replacement

devices, and otherwise failed to adequately test and study such devices for use as hip replacement devices before introducing them into the marketplace, rendered the devices, including the device implanted in Plaintiff, unsafe, defective and unreasonably dangerous for their intended use as hip replacement devices.

53. As a result of the design defects, manufacturing defects, failure to provide adequate warnings and the other circumstances which rendered the Zimmer hip replacement devices implanted in the Plaintiff unsafe, dangerous, and defective, this device did not meet the reasonable expectations of Plaintiff and/or Plaintiff's implanting physician with regard to safety and effectiveness when used for its intended purpose.

54. As a direct and proximate result of the design defects, manufacturing defects, failure to provide adequate warnings and other circumstances which rendered the Zimmer hip replacement device implanted in the Plaintiff unsafe, defective and unreasonably dangerous, Plaintiff has suffered and will continue to suffer severe physical harm, injuries to the Plaintiff's hip and leg, spinal nerve roots, and surrounding nerves, tissues, cells and vascular structures. As a result, Plaintiff has in the past and will in the future suffer a loss of earnings, an impairment in earning capacity, physical pain, mental anguish, emotional distress, disability, liabilities for medical and rehabilitative expenses and other forms of injury, loss and damage.

AS AND FOR A FIFTH CAUSE OF ACTION: Negligence

55. Plaintiff repeats and realleges each and every allegation set forth in the Paragraphs above and further alleges as follows:

56. The claims made in this Count of the Complaint are brought by Plaintiff against both Defendants.

57. In designing, promoting, marketing, distributing and selling the hip replacement

device which was implanted in Plaintiff, each Defendant was negligent and failed to exercise reasonable care in that, among other things, the device was poorly designed for its intended use as a hip replacement device because it could not bond or knit with the hip and/or leg bone did not possess a proper degree of rigidity.

58. In marketing, distributing, and selling the Zimmer medical device which injured Plaintiff, each defendant was negligent and failed to exercise reasonable care to assure that the device was properly manufactured.

59. In designing, promoting, marketing, distributing, and selling the Zimmer hip replacement device which injured Plaintiff, for its intended use as a hip replacement device, Both Defendants was negligent and failed to exercise reasonable care in that it failed to conduct adequate or proper tests or studies with regard to the functioning, safety, indications and effectiveness of the device for that intended use.

60. In marketing, distributing, and selling the aforesaid Zimmer hip replacement device which injured Plaintiff for its intended use as a hip replacement, both Defendants were negligent and failed to exercise reasonable care by failing to provide appropriate warnings and instructions to Plaintiff and Plaintiff's physician concerning use of the device as a hip replacement device.

61. Both Defendants were negligent in that an ordinary prudent seller would not have put the device which injured Plaintiff on the market under the circumstances alleged in this Complaint.

62. Both Defendants were negligent in failing to obtain proper regulatory approvals and clearances before it put the device which injured Plaintiff on the market.

63. As a direct and proximate result of the negligence of both Defendants, Plaintiff has suffered and will continue to suffer severe physical harm, including injury to Plaintiff's hip, spinal

nerve roots, and surrounding nerves, tissues, cells, and vascular structures. As a result, Plaintiff has in the past and will in the future suffer a loss of earnings, an impairment in earning capacity, physical pain, mental anguish, emotional distress, disability, liabilities for medical and rehabilitative expenses and other forms of loss, harm and damage.

AS AND FOR A SIXTH CAUSE OF ACTION:

Breach of Implied Warranty of Merchantability

64. Plaintiff repeats and realleges each and every allegation set forth in the Paragraphs above and further alleges as follows:

65. The claims made in this Count of the Complaint are brought by Plaintiff against both Defendants.

66. Both Defendants are merchant that generally sells hip replacement devices.

67. By intentionally promoting and knowingly selling its devices for use as hip replacement devices, both Defendants impliedly warranted to Plaintiff and to Plaintiff's implanting physician that the hip replacement devices at issue here was merchantable, that it was proven safe and effective for hip replacement devices, that it was properly labeled, that it contained proper instructions for use as a hip replacement device and that the commercial distribution of the device as a hip replacement device was in compliance with all applicable laws, regulations and ordinances.

68. This implied warranty extended to Plaintiff as the ultimate consumer and user of both of Defendants device and/or products.

69. Defendants breached their warranty to Plaintiff in that the device which was sold by Defendants and surgically implanted into Plaintiff was unmerchantable, was not proven to be safe and effective as a hip replacement device, was not safe and effective, was not properly

labeled and was an adulterated and misbranded device sold in violation of applicable laws.

70. As a direct and proximate result of said Defendants' breach of implied warranty, Plaintiff has suffered and will continue to suffer severe physical harm, including injuries to the Plaintiff's hip, spinal nerve roots, and surrounding nerves, tissues, cells, and vascular structures. As a result, Plaintiff has in the past and will in the future suffer a loss of earnings, an impairment in earning capacity, physical pain, mental anguish, emotional distress, permanent disability, liabilities for medical and rehabilitative expenses and other forms of injury, harm, loss, and damage.

AS AND FOR A SIXTH CAUSE OF ACTION: BREACH OF IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE

71. Plaintiff repeats and realleges each and every allegation set forth in the Paragraphs above and further alleges as follows:

72. The claims made in this Count of the Complaint are brought by Plaintiff against both Defendants.

73. Defendants are merchants that generally sells hip replacement devices.

74. By intentionally promoting and knowingly selling its devices for use as hip replacement devices, both of the defendants impliedly warranted to Plaintiff and to Plaintiff's implanting physician that the hip replacement device at issue here was fit for the particular purpose, that it was proven safe and effective for a hip replacement device, that it was properly labeled, that it contained proper instructions for use as a hip replacement device, and that the commercial distribution of the device as a hip replacement device was in compliance with all applicable laws, regulations and ordinances.

75. This implied warranty extended to Plaintiff as the ultimate consumer and user of

Defendants' products.

76. Both Defendants breached its implied warranty to Plaintiff in that the device which was sold by said Defendants and surgically implanted into Plaintiff was not fit for the particular purpose, was not proven to be safe and effective as a hip replacement device, was not safe and effective, was not properly labeled and was an adulterated and misbranded device sold in violation of applicable laws.

77. As a direct and proximate result of said Defendants breach of implied warranty, Plaintiff has suffered, and will continue to suffer severe physical harm, including injuries to the Plaintiff's hip, leg, spinal nerve roots, and surrounding nerves, tissues, cells, and vascular structures. As a result, Plaintiff has in the past and will in the future suffer a loss of earnings, an impairment in earning capacity, physical pain, mental anguish, emotional distress, permanent disability, liabilities for medical and rehabilitative expenses and other forms of injury, harm, loss, and damage.

AS AND FOR A SEVENTH CAUSE OF ACTION: LOSS OF CONSORTIUM

78. Plaintiff repeats and realleges each and every allegation set forth in the Paragraphs above and further alleges as follows:

79.. The claims made in this Count of the Complaint are made by Plaintiff's spouse against all Defendants named herein.

80. As a direct and proximate result of the conduct of Defendants and the acts alleged herein and the resulting physical injuries to Plaintiff, Plaintiff's spouse has suffered and will continue to suffer a loss of consortium, a loss of the love and affection, and a loss of the services of Plaintiff.

Prayer For Relief

WHEREFORE, Plaintiff and Plaintiff's spouse respectfully pray that the Court enter judgment in their favor and against the Defendants herein for compensatory damages in the amount of $1,000,000.00, punitive damages, in the amount to be determined where appropriate, reimbursement of all medical and related expenses, statutory interest, costs, attorney's fees and such other and further relief as may be just and appropriate.

Jury Demand

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure Plaintiff hereby demands trial by jury of all issues so triable.

Respectfully submitted,

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